**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF NEW YORK**

| | | |
|---|---|---|
| CHRISTEL BILLHOFER, On Behalf of Herself and All Others Similarly Situated, | : | |
| Plaintiff, | : | Civ. No. 07 Civ. 9920 (CSH) |
| vs. | : | (ECF Case) |
| FLAMEL TECHNOLOGIES, SA, STEPHEN H. WILLARD, and RAFAEL JORDA, | : | |
| Defendants. | : | |

**DECLARATION OF DAVID WERTHEIMER**
**IN SUPPORT OF THE MOTION TO DISMISS**
**BY FLAMEL TECHNOLOGIES, SA**

David Wertheimer
Peter Dennin
HOGAN & HARTSON LLP
875 Third Avenue
New York, New York 10022
Tel: (212) 918-3000
Fax: (212) 918-3100

Counsel for Defendant
Flamel Technologies, SA

Dated: May 12, 2008

I, David Wertheimer, do hereby declare as follows:

**1.** I am a member of the Bar of the State of New York and of this Court. I am also a member of the firm of Hogan & Hartson LLP, counsel for defendant Flamel Technologies, SA ("Flamel"). I make this declaration in support of Flamel's motion to dismiss, with prejudice, the amended complaint, dated March 27, 2008.

**2.** Attached hereto as Exhibit A is a true and correct copy of Christel Billhofer's "Certification of Named Plaintiff Pursuant to Federal Securities Law," sworn to November 1, 2007, which was filed with the Court in this action.

**3.** Attached hereto as Exhibit B are true and correct copies of selected pages from Flamel's Form 20-F for its fiscal year ending December 31, 2006, dated April 27, 2007, which was filed with the Securities and Exchange Commission.

**4.** Attached hereto as Exhibit C is a true and correct copy of an abstract which appeared in 13 *Journal of Cardiac Failure* S135 (August 2007), written by James E. Udelson, et al., entitled *Compliance with Once Daily Controlled Release vs Twice Daily Immediate Release Carvedilol in Patients with Heart Failure: The Casper Trial*, available at http://download.journals.elsevierhealth.com/pdfs/journals/1071-9164/PIIS1071916407007075.pdf.

**5.** Attached hereto as Exhibit D are true and correct copies of materials posted at the website http://clinicaltrials.gov/ct2/show/record/NCT00272805, entitled *Drug Compliance and Quality of Life in Patients with Heart Failure Dosed with Either Once-Daily or Twice-Daily Coreg*.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 12th day of May, 2008.

/s/
David Wertheimer

**CERTIFICATE OF SERVICE**

I hereby declare that on May 12, 2008, I caused a true and correct copy of the foregoing to be electronically filed and to be served, by United States Mail, first-class postage prepaid on counsel for plaintiff at the following address:

Samuel H. Rudman
David A. Rosenfeld
Coughlin Stoia Geller Rudman & Robbins LLP
58 South Service Road, Suite 200
Melville, NY 11747

/s/
David Wertheimer

CERTIFICATION OF NAMED PLAINTIFF
PURSUANT TO FEDERAL SECURITIES LAWS

CHRISTEL BILLHOFER ("Plaintiff") declares:

1. Plaintiff has reviewed a complaint and authorized its filing.

2. Plaintiff did not acquire the security that is the subject of this action at the direction of plaintiff's counsel or in order to participate in this private action or any other litigation under the federal securities laws.

3. Plaintiff is willing to serve as a representative party on behalf of the class, including providing testimony at deposition and trial, if necessary.

4. Plaintiff has made the following transaction(s) during the Class Period in the securities that are the subject of this action:

**Acquisitions:**

| Date Acquired | Number of Shares Acquired | Acquisition Price Per Share |
|---|---|---|
| 4/24/07 | 400 | 29.60 |
| 4/24/07 | 500 | 29.60 |
| | | |

**Sales:**

| Date Sold | Number of Shares Sold | Selling Price Per Share |
|---|---|---|
| | | |
| | | |
| | | |

5. Plaintiff has not sought to serve or served as a representative party for a class in an action filed under the federal securities laws except as detailed below during the three years prior to the date of this Certification:

6. The Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond the Plaintiff's pro rata share of any recovery,

except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 1 day of Nov, 2007.

CHRISTEL BILLHOFER



FLAMEL

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 20-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

**OR**

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the fiscal year ended December 31, 2006**

**OR**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from _____to _____**

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**Date of event requiring this shell company report _____**

**Commission file number: 000-28508**
**Flamel Technologies S.A.**

(Exact name of Registrant as specified in its charter)

**Not Applicable**
(Translation of Registrant's name into English)

**Republic of France**
(Jurisdiction of incorporation or organization)

**Parc Club du Moulin a Vent**
**33, avenue du Docteur Georges Levy**
**69693 Vénissieux Cedex France**
(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

| Title of each class | Name of Exchange on which Registered |
|---|---|
| **Ordinary Shares, nominal value 0.122 Euros per share, represented by American Depositary Shares (as evidenced by American Depositary Receipts), each representing one Ordinary Share** | **NASDAQ Global Market** |

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

[update] 23,990,590 Ordinary Shares, nominal value 0.122 Euros per Ordinary Share

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☑

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934.

Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐ Accelerated filer ☑ Non-accelerated filer ☐

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ☐ Item 18 ☑

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☑

**Risk Factors:**

Certain statements made in this annual report on Form 20-F are forward-looking statements based on our current expectations, assumptions, estimates and projections about our business and our industry. These forward-looking statements involve risks and uncertainties. Our business, financial condition and results of operations could differ materially from those anticipated in these forward-looking statements as a result of certain factors, as more fully described below and elsewhere in this annual report. The risks and uncertainties described below are not the only ones we face.

***We depend on a few customers for the majority of our revenues, and the loss of any one of these customers could reduce our revenues significantly.***

We depend on a few customers and partners for the majority of our revenues, particularly GlaxoSmithKline. The termination of our relationship with any of these major customers or partners and our failure to broaden our customer base, could cause our revenues to decrease significantly and result in losses from our operations. Further, we may be unable to negotiate favorable business terms with customers and partners that represent a significant portion of our revenues. If so, our revenues and gross profits, if any, may not grow as expected or may not grow at a rate sufficient to allow us to enjoy profitability.

***Our revenues depend on pharmaceutical and biotechnology companies successfully developing products that incorporate our drug delivery technologies.***

We market and sell our technologies to third parties, who incorporate our technologies into their products. We depend upon collaborative agreements with pharmaceutical and biotechnology companies to develop, test, obtain regulatory approval for and commercialize products that incorporate our drug delivery technologies. We currently have collaborative agreements or relationships with GlaxoSmithKline, Servier, Merck, and other unnamed pharmaceutical and biotechnology companies.

The number of products that our partners successfully develop under these collaborative agreements will affect our revenues. We cannot control the timing and other aspects of the development or marketing by our pharmaceutical and biotechnology company partners of their products that incorporate our technologies. The failure of one or more of our partners to develop successful products that incorporate our technologies or to perform as we expect under our agreements with them could have a material and adverse impact on our revenues and profits. We face risks relating to our collaborative agreements, including risks that:

- our collaborative agreements may not result in any new commercial products;
- the existing commercial products developed under our collaborative agreements may not be successful;
- our pharmaceutical and biotechnology company partners may not successfully market any commercial products;
- we may not be able to meet the milestones established in our current or future collaborative agreements;
- we may not be able to successfully develop new drug delivery technologies that would be attractive to potential pharmaceutical or biotechnology company partners; and
- our collaborative partners may terminate their relationships with us.

***Although products that incorporate our drug delivery technologies may appear promising at their early stages of development and in clinical trials, none of these potential products may reach the commercial market for a number of reasons.***

Successful research and development of pharmaceutical products is difficult, expensive, and time consuming. Many product candidates fail to reach the market. Accordingly, it is possible that products that incorporate our technologies may never reach the commercial market for any number of reasons. We intend to continue to enhance our current technologies and pursue additional proprietary drug delivery technologies. Our success will depend on the discovery and the successful commercialization of products that can utilize our drug delivery technologies. If products using our technologies fail to reach the commercial market, our revenues would be adversely affected, and we may be unable to increase our revenue.

**SIGNATURES**

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

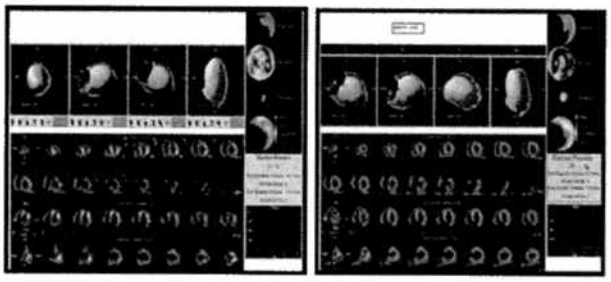
FLAMEL TECHNOLOGIES S.A.
(Registrant)

_____

Stephen H. Willard
Chief Executive Officer

Date:April 27, 2007

functional class. At 1 year, NYHA class improved in 92% of the patients in the BMC group by at least 1 class and no improvement in the control group. Mean improvements of LVEF post BMC transplantation were 5.0% and 7.4% at rest and stress SPECT respectively. Either rest and stress LVEF differences at one-year follow up and baseline between the BMC and control groups demonstrated significant difference; with rest LVEF was 4.8% vs 1.1% (p = 0.016) and with stress LVEF was 7.4% vs 0.08% (p = 0.001). **Conclusions:** Infusion of progenitor cells into the coronary sinus is safe and feasible in the ischemic HF patients. It is associated with significant improvement in symptoms, functional capacity and LVEF. Larger randomized studies are in progress.



*Gated Spect Stress EF. Note the increased of 8% in the EF at 1 year evaluation.*

## 208

**Atrial Fibrillation and Mortality in Patients Enrolled in the African American Heart Failure Trial**

Judith E. Mitchell[1], S. William Tam[2], Kamini Trivedi[2], Michael L. Sabolinski[2], Manuel Worcel[2]; [1]Medicine/Cardiology, State University of New York Downstate Medical Center, Brooklyn, NY; [2]NitroMed, Inc., Lexington, MA

**Background:** Atrial fibrillation (AF) is common in patients (pts) with heart failure (HF) and portends a worsened prognosis. African American (AA) pts with HF have a higher morbidity and mortality than the general HF population. Because of the low enrollment of AA in randomized HF trials, not much is known of AF in HF in this cohort. We sought to evaluate morbidity and mortality in pts enrolled in the African American Heart Failure Trial (A-HeFT). **Methods:** 1050 AA pts with NYHA class III/IV systolic HF, well treated (87% beta-blockers, 93% ACEI and/or ARB), were randomized to added fixed-dose combination of isosorbide dinitrate/hydralazine (FDC I/H) or placebo. **Results:** AF recorded in 174 (16.6%) pts at baseline and 183 (17.4%) combined baseline plus new development of AF during mean 12.8-month follow-up. Comparison of pts with AF vs. no AF revealed: mean age 61 ± 12 vs. 56 ± 13 yr (p < 0.001); systolic BP 124 ± 18 vs. 127 ± 18 mmHg (p = 0.044), diastolic BP 74 ± 11 vs. 77 ± 10 (p = 0.002); creatinine 1.4 ± 0.5 vs. 1.2 ± 0.5 (p < 0.001) and BNP 431 ± 443 vs. 283 ± 396 (p < 0.001). No significant difference was observed in ejection fraction, left ventricular end diastolic diameter or Quality of Life scores. However, survival differed significantly between AA pts with and without AF, (Fig 1A) and the use of FDC I/H influenced that survival (Fig 1B). **Conclusion:** AA with HF and AF (vs. no AF) were older, had lower BP and higher creatinine and BNP levels. They also had lower survival. The use of FDC I/H significantly improved survival in these high-risk HF patients.

Fig. 1A. Effect of Atrial Fibrillation at Baseline or During Trial on Survival

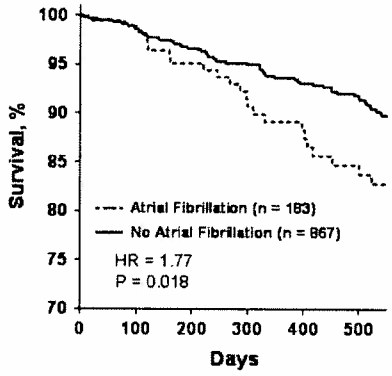
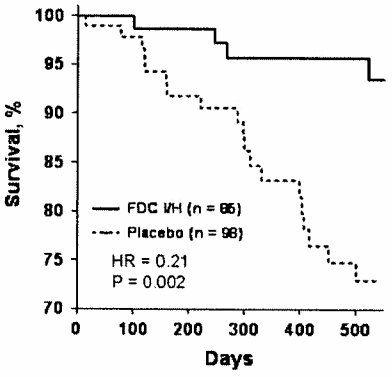



Fig. 1B. Effect of FDC I/H on Survival in Patients with Atrial Fibrillation




## 209

**Compliance with Once Daily Controlled Release vs Twice Daily Immediate Release Carvedilol in Patients with Heart Failure: The CASPER Trial**

James E. Udelson[1], Susan J. Pressler[2], Jonathan Sackner-Bernstein[3], Mary Ann Lukas[4], Paul A. Ordronneau[4], Joseph Massaro[5], Paul Hauptman[6]; [1]Tufts-NEMC, Boston; [2]Indiana Univ Nursing, Indianapolis; [3]ClinLabs Inc., NY, NY; [4]GSK, Phil, PA; [5]Boston Univ, Boston, MA

**Background:** Once daily (QD) vs twice daily (BID) dosing may increase compliance, thereby increasing effective daily dosage. The CASPER Trial was designed to measure differential compliance, quality of life (QOL) and satisfaction with medication in chronic heart failure (HF) patients taking BID carvedilol immediate release (Carv IR) vs bioequivalent QD Carv controlled release (CR). **Methods:** HF pts with LV EF < 40% on > 2 mos stable Carv IR BID were randomized to either group A: staying on Carv IR BID double blind, group B: switched to equivalent dose carv CR in AM and placebo in PM, double blind, or Group C: switched to open label equivalent dose carv CR QD. Compliance was measured by medication event monitoring system caps, and QOL by KCCQ and other instruments (including TSQM - satisfaction wth treatment) over 5 months. Sample size assumed 75% BID compliance and 90% QD compliance. Primary endpoint was "taking compliance" (% correct doses/doses prescribed). 405 pts were randomized at 55 US sites (62% HF specialists). Mean age was 65 yrs, mean LVEF 29%, 64% NYHA class II, with > 90% taking ACEi/ARB and 100% on Carv IR BID. **Results:** see Table. There were also no differences in change in NYHA class. Adverse events were reported in 56% of pts staying on their Carv IR BID and in 58% of pts switched to Carv CR (p = NS). There was no difference in serious adverse events between groups. **Conclusions:** Switching from Carv IR BID to Carv CR QD in this trial setting was not associated with better drug taking compliance, in part due to higher than anticipated compliance in the BID cohort. Switching from Carv IR to Carv CR was well tolerated, with no adverse events or safety issues associated with switching.

Results

| Group | A (Carv IR BID) | B (Carv CR/Plac) | C (Carv CR QD | |
|---|---|---|---|---|
| | n = 133 | n = 136 | n = 136 | p |
| Taking compliance (%) | 89 +/− 21 | 87 +/− 25 | 88 +/−24 | NS |
| Correct dosing days (%) | 86 +/− 20 | 85 +/− 25 | 87 +/− 25 | NS |
| KCCQ Δ >= 5 (% of pts) | 34 | 23 | 28 | NS |
| Δ median BNP (IQR) (pg/ml) | − 4 (−337, 418) | − 1 (−855, 1556) | 0 (−632, 1828) | NS |
| Δ TSQM score | −3 +/− 18 | −4 +/− 20 | −1 +/− 21 | NS |

## 210

**Withdrawn**

## 211

**Sildenafil Improves Exercise Capacity and Quality of Life in Patients with Systolic Heart Failure and Secondary Pulmonary Hypertension**

Gregory D. Lewis[1], Ravi Shah[1], Khurram Shahzad[1], Janice Camuso[1], Paul P. Pappagianopoulos[2], Judy Hung[1], Ahmed Tawakol[1], Robert E. Gerszten[1], David M. Systrom[2], Kenneth D. Bloch[3], Marc J. Semigran[1]; [1]Internal Medicine, Cardiology Division, Massachusetts General Hospital, Boston, MA; [2]Internal Medicine, Pulmonary Critical Care Unit, Massachusetts General Hospital, Boston, MA; [3]Anesthesia, Massachusetts General Hospital, Boston, MA

**Background:** Patients with systolic heart failure (HF) who develop secondary pulmonary hypertension (PH) have reduced exercise capacity and increased mortality

# Drug Compliance and Quality of Life in Patients With Heart Failure Dosed With Either Once-Daily or Twice-Daily Coreg

**This study is ongoing, but not recruiting participants.**

| | |
|---|---|
| **Sponsors and Collaborators:** | **Cardiovascular Clinical Studies**<br>GlaxoSmithKline |
| **Information provided by:** | Cardiovascular Clinical Studies |
| **ClinicalTrials.gov Identifier:** | NCT00272805 |

## ▶ Purpose

The purpose of this study is to compare dosing compliance between study patients taking controlled release carvedilol once a day, and study patients taking immediate release carvedilol (Coreg) twice a day.

| Condition | Intervention | Phase |
|---|---|---|
| Chronic Heart Failure | Drug: carvedilol | Phase III |

ChemIDplus related topics: Carvedilol

U.S. FDA Resources

Study Type: Interventional
Study Design: Treatment, Randomized, Double-Blind, Active Control, Parallel Assignment

Official Title: Prospective, Randomized, Controlled Assessment of Once-Daily Controlled Release COREG CR Vs Twice-Daily COREG Immediate Release(IR)on Measures of Compliance and Quality of Life in Patients With Heart Failure and Left Ventricular Systolic Dysfunction

**Further study details as provided by Cardiovascular Clinical Studies:**

Primary Outcome Measures:

- Dosing compliance: pill taking total taken vs number prescribed

Secondary Outcome Measures:

- quality of life

Estimated Enrollment: 400

Study Start Date: October 2005

**Detailed Description:**

Study Further Study Details:

Primary outcome: pill-taking compliance (total doses taken versus total doses prescribed)

Expected Total Enrollment: 400 subjects at 56 study sites in the U.S.

Study Start: October 2005

This is a 5-month double-blind treatment study of male and female subjects with stable mild-to-severe chronic heart failure and with left ventricular dysfunction with symptoms of heart failure.

Eligibility:

Must be stable on treatment with Coreg IR at a standard dose: 6.25, 12.5, 25 mg twice a day.

## ▶ Eligibility

Ages Eligible for Study: 18 Years to 90 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Inclusion Criteria:

- Ability to read English
- Stable symptoms of mild to severe heart failure
- Stable medical regimen for heart failure
- On a stable dose of Coreg for at least 2 months
- LVEF ⩽40% within the previous 24 months

Exclusion Criteria:

- Uncorrected obstructive or regurgitant valve disease
- Complex congenital heart disease
- Recent ICD or pacemaker placement
- Recent coronary artery bypass surgery or stroke
- Candidate for heart transplanct within 5 months of study start
- Present or planned use of MAO inhibitors, alfpha-blockers, combined alpha-beta blockers, any Class I/II anti-arrythmnic agents, (amiodarone may be used if ⩽ 200mg/day). Use of intravenous vasodilator/inotropic agents.

## ▶ Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT00272805

**Show 54 Study Locations**

**Sponsors and Collaborators**

**Cardiovascular Clinical Studies**

GlaxoSmithKline

**Investigators**

Principal Investigator: James E. Udelson, M.D. Cardiovascular Clinical Studies, Inc.

## More Information

| | |
|---|---|
| Study ID Numbers: | CCS 2005-001, CASPER |
| First Received: | January 5, 2006 |
| Last Updated: | February 6, 2006 |
| ClinicalTrials.gov Identifier: | NCT00272805 |
| Health Authority: | United States: Food and Drug Administration |

Keywords provided by Cardiovascular Clinical Studies:
chronic heart failure
left ventricular systolic dysfunction

Study placed in the following topic categories:
Heart Failure
Heart Diseases
Quality of Life
Carvedilol

Additional relevant MeSH terms:

| | |
|---|---|
| Neurotransmitter Agents | Antihypertensive Agents |
| Vasodilator Agents | Pharmacologic Actions |
| Adrenergic Agents | Therapeutic Uses |
| Molecular Mechanisms of Pharmacological Action | Adrenergic beta-Antagonists |
| Physiological Effects of Drugs | Cardiovascular Diseases |
| Cardiovascular Agents | Adrenergic Antagonists |
| Adrenergic alpha-Antagonists | |

ClinicalTrials.gov processed this record on May 08, 2008

# Drug Compliance and Quality of Life in Patients With Heart Failure Dosed With Either Once-Daily or Twice-Daily Coreg

**This study is ongoing, but not recruiting participants.**

Information provided by Cardiovascular Clinical Studies

**This Tabular View shows the required WHO registration data elements as marked by †**

## Descriptive Information Fields

| | |
|---|---|
| **Brief Title †** | Drug Compliance and Quality of Life in Patients With Heart Failure Dosed With Either Once-Daily or Twice-Daily Coreg |
| **Official Title †** | Prospective, Randomized, Controlled Assessment of Once-Daily Controlled Release COREG CR Vs Twice-Daily COREG Immediate Release(IR)on Measures of Compliance and Quality of Life in Patients With Heart Failure and Left Ventricular Systolic Dysfunction |
| **Brief Summary** | The purpose of this study is to compare dosing compliance between study patients taking controlled release carvedilol once a day, and study patients taking immediate release carvedilol (Coreg) twice a day. |
| **Detailed Description** | Study Further Study Details:<br><br>Primary outcome: pill-taking compliance (total doses taken versus total doses prescribed)<br><br>Expected Total Enrollment: 400 subjects at 56 study sites in the U.S.<br><br>Study Start: October 2005<br><br>This is a 5-month double-blind treatment study of male and female subjects with stable mild-to-severe chronic heart failure and with left ventricular dysfunction with symptoms of heart failure.<br><br>Eligibility:<br><br>Must be stable on treatment with Coreg IR at a standard dose: 6.25, 12.5, 25 mg twice a day. |
| **Study Phase** | Phase III |
| **Study Type †** | Interventional |
| **Study Design †** | Treatment, Randomized, Double-Blind, Active Control, Parallel Assignment |
| **Primary Outcome Measure †** | Dosing compliance: pill taking total taken vs number prescribed |

| | |
|---|---|
| **Secondary Outcome Measure †** | quality of life |
| **Condition †** | Chronic Heart Failure |
| **Intervention †** | Drug: carvedilol |
| **MEDLINE PMIDs** | |
| **Links** | |

## Recruitment Information Fields

| | |
|---|---|
| **Recruitment Status †** | Active, not recruiting |
| **Enrollment †** | 400 |
| **Start Date †** | October 2005 |
| **Completion Date** | |
| **Eligibility Criteria †** | Inclusion Criteria:<br>• Ability to read English<br>• Stable symptoms of mild to severe heart failure<br>• Stable medical regimen for heart failure<br>• On a stable dose of Coreg for at least 2 months<br>• LVEF ⩽40% within the previous 24 months<br><br>Exclusion Criteria:<br>• Uncorrected obstructive or regurgitant valve disease<br>• Complex congenital heart disease<br>• Recent ICD or pacemaker placement<br>• Recent coronary artery bypass surgery or stroke<br>• Candidate for heart transplanct within 5 months of study start<br>• Present or planned use of MAO inhibitors, alfpha-blockers, combined alpha-beta blockers, any Class I/II anti-arrythmnic agents, (amiodarone may be used if ⩽ 200mg/day). Use of intravenous vasodilator/inotropic agents. |
| **Gender** | Both |
| **Ages** | 18 Years to 90 Years |
| **Accepts Healthy Volunteers** | No |
| **Contacts ††** | |
| **Location Countries †** | United States |

## Administrative Information Fields

| | |
|---|---|
| **NCT ID** † | NCT00272805 |
| **Organization ID** | CCS 2005-001 |
| **Secondary IDs** †† | CASPER |
| **Study Sponsor** † | Cardiovascular Clinical Studies |
| **Collaborators** †† | GlaxoSmithKline |
| **Investigators** † | Principal Investigator: James E. Udelson, M.D. Cardiovascular Clinical Studies, Inc. |
| **Information Provided By** | Cardiovascular Clinical Studies |
| **Verification Date** | February 2006 |
| **First Received Date** † | January 5, 2006 |
| **Last Updated Date** | February 6, 2006 |

† **Required WHO trial registration data element.**
†† **WHO trial registration data element that is required only if it exists.**



# Drug Compliance and Quality of Life in Patients With Heart Failure Dosed With Either Once-Daily or Twice-Daily Coreg

**This study is ongoing, but not recruiting participants.**
Information provided by Cardiovascular Clinical Studies

**Please refer to this study by its ClinicalTrials.gov identifier: NCT00272805**

## Locations

**United States, Alabama**
The Heart Group
Mobile, Alabama, United States, 36608

**United States, Arizona**
Radiant Research
Sierra Vista, Arizona, United States, 85635

**United States, California**
Northern California Medical Associates
Santa Rosa, California, United States, 95403
San Diego Cardiac Center
San Diego, California, United States, 34203
Radiant Research
Santa Rosa, California, United States, 95405
Cardiology Consultants of Orange County
Anaheim, California, United States, 92801
Access Clinical Trials
Beverly Hills, California, United States, 90210
Cardiovascular Consultants Medical Group
Walnut Creek, California, United States, 94598
Cardiovascular Consultants Medical Group
Oakland, California, United States, 94609

**United States, Colorado**
Heart Center of the Rockies
Fort Collins, Colorado, United States, 80528

**United States, Connecticut**
St. Francis Hospital and Medical Center
Hartford, Connecticut, United States, 06105

**United States, Florida**

NextPhase Clinical Trials
Miami, Florida, United States, 33126

Charlotte Heart Group Research Center
Port Charlotte, Florida, United States, 33952

The Heart and Vascular Institute of Florida
St. Petersburg, Florida, United States, 33701

**United States, Georgia**

CVMS Research Institute of Augusta
Augusta, Georgia, United States, 30901

Georgia Heart Specialists
Covington, Georgia, United States, 30014

Cardiac Disease Specialists
Atlanta, Georgia, United States, 30309

**United States, Idaho**

Idaho Cardiology Associates
Boise, Idaho, United States, 83704

**United States, Illinois**

North Shore Cardiologists
Bannockburn, Illinois, United States, 60015

Illinois Heart and Lung Research Center
Normal, Illinois, United States, 61761

Midwest Heart Foundation
Lombard, Illinois, United States, 60148

**United States, Indiana**

The Care Group
Indianapolis, Indiana, United States, 46260

**United States, Louisiana**

Clinical Trials Management
Metairie, Louisiana, United States, 70006

**United States, Maine**

Cardiovascular Consultants of Maine
Scarborough, Maine, United States, 04074

Androscoggin Cardiology Associates-Research
Auburn, Maine, United States, 04210

Maine Cardiology Associates
S. Portland, Maine, United States, 04106

**United States, Massachusetts**

Pentucket Medical Associates
Haverhill, Massachusetts, United States, 01830

Primary Care Cardiology Research

Ayer, Massachusetts, United States, 01432
Lahey Clinic Cardiology
Burlington, Massachusetts, United States, 01805

**United States, Michigan**
Henry Ford Hospital
Detroit, Michigan, United States, 48202

**United States, Nebraska**
Bryan LGH Heart Institute
Lincoln, Nebraska, United States, 68516

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